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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/939,863	08/27/2001	Michael Milboker	Praxis-3	7242

7590

01/12/2005

PROMETHEAN SURGICAL DYNAMICS LLC
3 GILL ST. #FIG
WOBBURN, MA 01801

EXAMINER

PREBILIC, PAUL B

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 01/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<p align="center">Office Action Summary</p>	<p>Application No.</p> <p>09/939,863</p>	<p>Applicant(s)</p> <p>MILBOCKER, MICHAEL</p>	
	<p>Examiner</p> <p>Paul B. Prebilic</p>	<p>Art Unit</p> <p>3738</p>	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 and 17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 13 and 17 is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>8/11/04</u> . | 6) <input type="checkbox"/> Other: _____ |

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 12, 2004 has been entered.

Claim Objections

Claims 11 and 13 are objected to because of the following informalities:

On the last line of claim 11, the word "or" should be ---and--- in order to be consistent with accepted language for Markush listing; see MPEP 2173.05(h).
Appropriate correction is required.

On line 3 of claim 13, the language is grammatically awkward or lacks clear antecedent basis. The Examiner suggests changing "suturing said absorbent pad" to ---suturing said at least one absorbent pad--- in order to overcome this objection.
Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 5, and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Sawyer (US 5,156,613). Sawyer anticipates the claim language where the prosthetic as claimed is the collagen filler material (60) of Sawyer; see Figure 3 as well as column 7, line 61 to column 8, line 47, the abstract and column 2, lines 23-51. The prosthetic coating as claimed is the fibrin glue or adhesive coated over the filler material; see column 8, lines 22-33.

Claims 1, 2, and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Kreamer (US 4,577,631). Kreamer anticipates the claim language where the graft is the prosthetic as claimed; see the abstract, column 2, lines 24-35 and column 6, line 31 to column 7, line 17.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Polson et al (US 5,487,897) alone. Polson et al discloses an embodiment with a formed implant that is applied to a wound site with adhesive but lacks the step of applying adhesive to the implant before application to the tissue; see the abstract; column 3, lines 31-54, column 4, lines 43-46; column 16, lines 58 to column 17, line 13 and column 18, lines 33-38. However, at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to apply adhesive also to

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the implant because Applicants have not disclosed that applying adhesive to the prosthetic provides some advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicants' invention to perform equally well because the adhesive merely needs to be between the tissue and prosthetic surfaces to function properly. It does not matter whether it is applied to one surface, the other surface, or to both surfaces. Therefore, it would have been an obvious matter of design choice to modify Polson to obtain the invention as specified in the claims.

Claims 4-6 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Polson et al (US 5,487,897) in view of English et al (US 4,804,691). Polson fails to disclose the specific types of adhesives used therewith as claimed. However, English teaches that fibrin, polyurethane, and polyisocyanate adhesives were known and available to the art at the time the invention was made; see column 1, lines 21-61. Therefore, it would have been prima facie obvious to an ordinary artisan to substitute any of these other known surgical adhesives for the adhesive of Polson for the same reasons that the prior art used the same and to adapt the device to the particular patient's need.

Claims 4, 6, and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sawyer et al (US 5,156,613) in view of English et al (US 4,804,691). Sawyer fails to disclose the types of adhesives as claimed. However, English teaches that fibrin, polyurethane, and polyisocyanate adhesives were known and available to the art at the time the invention was made; see column 1, lines 21-61. Therefore, it would have

been prima fascia obvious to an ordinary artisan to substitute any of these other known surgical adhesives for the adhesive of Sawyer for the same reasons that the prior art used the same and to adapt the device to the particular patient's need.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Polson et al (US 5,487,897) in view of Owen et al (US 6,211,335). Polson fails to disclose the use of albumin solder as claimed. However, Owen teaches that it was known to use albumin solder in similar tissue bonding methods; see column 9, lines 7-14. Hence, it is the Examiner's position that it would have been prima fascia obvious to substitute or combine the albumin solder of Owen for/with the adhesive of either Polson for the same reasons that Owen uses the same and in order to adapt the Polson device to the particular patient need.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Polson et al (US 5,487,897) or Sawyer (US 5,156,613) in view of Ganster et al (US 6,191,216). Polson or Sawyer fails to disclose the use of open cell polyurethane adhesive as claimed. However, Ganster teaches that it was known to use foamed (open cell) polyurethane adhesive in similar tissue bonding methods; see column 1, lines 11-39 and column 6, lines 38-47. Hence, it is the Examiner's position that it would have been prima fascia obvious to substitute or combine the foamed adhesive of Ganster for/with the adhesives of either Polson or Sawyer for the same reasons that Ganster uses the same and in order to adapt the Polson or Sawyer devices to the particular patient need.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sawyer et al (US 5,156,613) alone. Sawyer meets the claim language as set forth above, but

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fails to disclose the repair of an inguinal hernia as claimed. However, since Sawyer et al teaches that the method thereof can be used for any internal surgical repair (see previous citations), it would have been prima facie obvious to use the Sawyer device to repair an inguinal hernia so as to help such patients also.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Polson et al as applied to claim 1, and further in view of Zhu et al (US 6,589,897). Polson renders claim 1 obvious as explained supra, but fails to disclose the use of polytetrafluoroethylene or fibrotic polypropylene stimulator material as the support material as claimed; see supra, particularly the column 9, line 62 to column 10, line 4 and claim 30. However, Zhu teaches that it was known to use polytetrafluoroethylene (i.e. PTFE) in similar tissue patches in the art; see column 3, line 66 to column 4, line 4. Therefore, it is the Examiner's position that it would have been considered prima facie obvious to use PTFE as the support layer of Polson because of the reasons that Zhu uses the same.

Allowable Subject Matter

Claims 13 and 17 are allowed over the prior art of record.

Response to Arguments

Applicant's arguments filed August 11 and October 12, 2004 have been fully considered but they are not persuasive.

Applicant argues that Sawyer does not meet the claim language of claim 1 because he says that only collagen melting not gluing with fibrin repairs the tissue. The Examiner asserts that the claimed method is read on by Sawyer even though Sawyer

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has additional steps not claimed. This is due to the fact that the method of tissue repair 'comprises' the claimed steps.

Next, Applicant argues that the Examiner has used hindsight to apply Polson to claim 1. It must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). The rationale used set forth in the rejection give adequate explanation as to why the claim language is clearly obvious.

In response to the traversal that English teaches away from using adhesive other than the particular one disclosed thereby, the Examiner asserts that English merely prefers his particular adhesive because it has wider applicability; see MPEP 2144.06 which is incorporated herein by reference thereto. It is excerpted as follows:

A prima facie case of obviousness may also be rebutted by showing that the art, in any material respect, teaches away from the claimed invention. *In re Geisler*, 116 F.3d 1465, 1471, 43 USPQ2d 1362, 1366 (Fed. Cir. 1997) (Applicant argued that the prior art taught away from use of a protective layer for a reflective article having a thickness within the claimed range of "50 to 100 Angstroms." Specifically, a patent to Zehender, which was relied upon to reject applicant's claim, included a statement that the thickness of the protective layer "should be not less than about [100 Angstroms]." The court held that the patent did not teach away from the claimed invention. "Zehender suggests that there are benefits to be derived from keeping the protective layer as thin as possible, consistent with achieving adequate protection. A thinner coating reduces light absorption and minimizes manufacturing time and expense. Thus, while Zehender expresses a preference for a thicker protective layer

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of 200-300 Angstroms, at the same time it provides the motivation for one of ordinary skill in the art to focus on thickness levels at the bottom of Zehender's suitable' range- about 100 Angstroms- and to explore thickness levels below that range. The statement in Zehender that [i]n general, the thickness of the protective layer should be not less than about [100 Angstroms]' falls far short of the kind of teaching that would discourage one of skill in the art from fabricating a protective layer of 100 Angstroms or less. [W]e are therefore not convinced that there was a sufficient teaching away in the art to overcome [the] strong case of obviousness' made out by Zehender."). See MPEP § 2145, paragraph X.D., for a discussion of "teaching away" references.

Conclusion

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilic whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, McDermott Corrine can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Paul Prebilic
Primary Examiner
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